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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,204	06/22/2001	Moshe Fleshner-Barak	1662/53002	7559

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
11/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/887,204	FLESHNER-BARAK ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-96 and 113-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-96 and 113-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks filed 9/24/08. Claims 90, 93, 118, 120 and 121 are amended. New claims 126-131 are added. Claims 90-96 and 113-131 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/118/08 has been entered.

Filling Date of the Last Response

The examiner agrees with applicant that the response to the Office action of 06/04/2007 was filed 12/07/07 according to the records, and while applicant may have filed 12/04/07, the stamp and the records say 12/07/08. The indication that the response was filed 9/26/06 was inadvertent.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 90-96, 113-125 and new claims 126-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525) according to the rejections on record and reiterated herein.

Burnside discloses multiple pulsed dose drug delivery system (abstract) comprising a core (column 6, lines 52-56) that includes one or more amphetamine salts coated with immediate release coating and one or more amphetamine salts that are covered with enteric coating (column 3, lines 25-48; column 4), and additives, the additives are binders, disintegration agent, filling agent, surfactant, solubilizers and stabilizers (column 6, line 64; column 7, lines 1, 6, 11, 14 and 18). Hydroxypropyl methylcellulose is an example of a binder additive (column 6, lines 63-67); cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB),

crosslinked polyvinylpyrrolidone (PLASDONE XL) are examples of disintegration agents (column 7, lines 1-5); mannitol, lactose, polyethylene glycol are few of the fillers in Burnside (column 7, lines 6-10); PLURONIC is a surfactant in Burnside (column 7, lines 10-13); methylphenidate is specifically disclosed as an amphetamine derivative (column 7, lines 48-55).

The cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) meet the limitation of the claimed disintegration agents. Claims 113 and 114 recite the properties of the composition and the recited properties are inherent to the composition.

Claim 115 recites the characteristic of the particles and is met by the art.

Claims 116 and 117 administer the composition of claims 90 and 93 to a person in need thereof to treat hyperactivity and since Burnside administers the dosage form and acknowledges that that methylphenidate can treat attention deficit hyperactivity (column 7, lines 51-55), the administered dosage would inherently treat hyperactivity and new claims 116 and 117 are met.

The prior art teaches the presence hydroxypropyl methylcellulose, cross-linked carboxymethylcellulose and sodium starch glycolate so that claims 122-125 are met.

The particles of Burnside are coated with hydrophilic or hydrophobic polymers namely hydroxypropyl methylcellulose polyvinylpyrrolidone, ethylcellulose, EUDRAGIT polymers and other enteric polymers (column 7, line 42 to column 8, line 45) meeting new claims 118-121.

Burnside discloses a composition comprising disintegration agent and methylphenidate and the composition is multi-particulate with some cores coated with enteric coating material and others coated with immediate release coating materials. The formulation of Burnside does not contain tannic acid or tannin or gallotannin or gallotannic acid.

However, Methylphenidate has been known to be formulated with tannic acid for controlled solubility of the methylphenidate according to Swanson (column 4, lines 45-49; column 7, line 16, 44; column 8, line 16). The claims recite ranges in amounts of superdisintegrants, hydrogel and tannic acid. However, there is no demonstration that the recited amounts provide unexpected results to the claimed dosage form. Specifically, Burnside is silent in the amounts of these ingredients, which implies that any amount in any combination would provide formulation for the effective release of methylphenidate. New claims 126-131 are compositions comprising various amounts of tannic acid, hydroxypropylmethylcellulose and hydroxypropylcellulose and superdisintegrants and in that wise are similar to claim 90 except for the specific hydrogel materials of hydroxypropylmethylcellulose and hydroxypropylcellulose claims. Furthermore, the claimed broad ranges suggest varied combinations in varied amounts. In the absence of factual evidence, the recited amounts of the hydrogel composition, the tannic acid and the superdisintegrants would not distinguish the claimed invention over the prior art.

Therefore, taken the combined teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that inclusion of tannin or tannic acid into the composition of Burnside would provide controlled solubility of methylphenidate.

Response to Arguments

5. Applicant's arguments filed 9/24/08 have been fully considered but they are not persuasive.

Applicant argues:

a) that Burnside does not teach including tannic acid in its drug delivery system and "does not teach or suggest a formulation for gastric retention," and that Burnside does not teach or suggest that the amounts of hydrogel and superdisintegrants affect the expansion and strength of the formulation. While the examiner agrees with the applicant that Burnside fails to teach the inclusion of tannic acid in the formulation, it is noted that the rejection of the claims is made over multiple references, with the secondary reference curing the deficiency of the lack of tannic acid in the formulation of Burnside. Applicant appears to be arguing against the references individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With regards to applicant's arguments that Burnside does not teach or suggest gastric retention, it is noted that the claims are directed to formulations that are orally administrable and the formulation of Burnside is a tablet or capsule (abstract); the formulation of Swanson also takes the form of a capsule; the capsule and the tablet are orally administrable such that when the tablet is administered, the tablet composed of tannic acid, hydrogel and superdisintegrant would also have the characteristics of the claimed invention. Furthermore, it is noted, affecting the expansion and strength of a formulation is derived from the properties of the hydrogel and superdisintegrant noting that a composition and its characteristic properties cannot be separated. It is noted that the amounts claimed are broad ranges and applicant has not provided factual showing that the recited amounts in the range recited for the tannic acid, hydrogel and superdisintegrants provide unexpected results to the composition.

b) that the tannic acid in Swanson reacts with a base to form a salt and that the tannic acid is not there for enhancing expansion and strength of the matrix. This is not found persuasive because whether the tannic acid is present as an acid to react with a base or is present to enhance the expansion or strength of the matrix, both effects stem from the properties of the compound, which in this case is tannic acid. Since the properties of a compound or composition cannot be separated from the composition or compound, the tannic acid in Burnside is also capable of effecting enhancement of expansion and strengthening of the matrix. Furthermore, applicant appears to have different use for tannic acid and the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Tannic acid is tannic acid in the claims and if the tannic acid performs certain use in the claimed composition, it would also perform the function in the composition of Burnside.

c) The examiner disagrees with applicant that the examiner failed to provide reasons as to why a person of skill would modify Burnside by including tannic acid in its formulation because both Swanson and Burnside teach compositions containing methylphenidate and including the tannic acid of Swanson would provide controlled solubility of the methylphenidate. Both compositions would have the same utility since they are both directed to methyphenidate.

d) Therefore, Swanson provides what is missing in Burnside, the tannic acid.

e) Regarding the gastric retentive nature of the claimed composition, it is noted that the retention of the composition in the gastric is derived from the properties of the composition,

specifically, the polymers, hyroxypropylmethylcellulose, hydroxypropylcellulose, and since the composition of Burnside contains the hydxrogel polymers of hyroxypropylmethylcellulose, hydroxypropylcellulose, the composition of Burnside would also be retained. It is also noted that the claims are directed composition and the properties of the composition in terms of the gastric retentive nature is inherent.

It is further noted applicant does not provide factual showing that tannic acid does not provide enhanced expansion of the formulation; rather applicant's specification at paragraph 104 shows that it is the type of superdisintegrant that provides the expansion, because 5 wt% of tannic acid in combination with croscamellose showed 36 fold expansion, while 5 wt% tannic acid in combination with sodium starch glycolate showed 18 fold expansion.

Therefore, claims 90-96 and 113-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525).

6. Claims 90, 93, 116, 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525) and further in view of Baker et al. (US 5,874,090).

Burnside in view of Swanson has been shown above to render obvious claims 90 and 93 obvious. While Burnside recognizes that methylphenidate is indicated in the treatment of attention deficit hyperactivity disorder (column 7, lines 51-55), Burnside does not specifically describe treating attention deficit disorder. However, Baker teaches that methylphenidate can be administered to a subject in need thereof to treat hyperactivity (claims 1-10 and 16). Therefore, taking the teachings of Burnside, Swanson and Baker together, the person of ordinary skill in the

art at the time the invention was made would have reasonable expectation of success that administering the composition of Burnside containing the tannic acid of Swanson to person in need thereof, would treat hyperactivity as suggested by Baker.

Response to Arguments

7. Applicant's arguments filed 9/24/08 have been fully considered but they are not persuasive.

8. Applicant argues that Baker does not teach inclusion of hydrogel, superdisintegrant and tannic acid in the formulation and that Baker is not concerned with gastric retention. But, the rejection of the claims is over multiple references and applicant is arguing against the individual references. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With regards to the gastric retentive nature of the composition, it is noted that gastric retention is brought about by the polymer in the formulation. Burnside discloses composition containing the same types of polymer and would therefore exhibit gastric retentive. Applicant has not provided factual showing that the composition of Burnside in view of Baker cannot be retained in the gastric. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). It is also noted that Baker is relied upon to show that methylphenidate is administered to treat hyperactivity.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618